UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

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| STANLEY ROGER SPIER, | ) | |
| | ) | |
| Plaintiff, | ) | |
| | ) | |
| v. | ) | No.: 3:14-CV-550-TAV-HBG |
| | ) | |
| COLOPLAST CORPORATION, | ) | |
| | ) | |
| Defendant. | ) | |

**MEMORANDUM OPINION**

This civil action is before the Court on defendant Coloplast Corporation's motion to dismiss plaintiff's complaint [Doc. 8]. The complaint asserts four state-law causes of action arising out of the manufacture and sale of the Titan Inflatable Penile Prosthesis ("the Titan Prosthesis"): design defect, failure to warn, and breach of express and implied warranties [Doc. 1-1 p. 3–6]. Defendant contends each of these claims is either expressly preempted by federal law or otherwise inadequately pleaded and must be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) [Doc. 8 ¶¶ 3–4].

Plaintiff has failed to respond to defendant's motion, despite being granted additional time to do so. *See* E.D. Tenn. L.R. 7.2 ("Failure to respond to a motion may be deemed a waiver of any opposition to the relief sought."). The Court, nevertheless, has carefully considered the matter,[1] and will dismiss plaintiff's design defect, failure-to-

[1] In *Carver v. Bunch*, the Sixth Circuit clarified that, in certain situations, a district court abuses its discretion in dismissing a complaint solely for failure to respond to a defendant's motion to dismiss pursuant to Rule 12(b)(6). 946 F.2d 451, 455 (6th Cir. 1991) (noting that its holding "is not meant to impair the district court's authority to dismiss a plaintiff's action under Rule 41(b) for a failure to prosecute").

warn, and implied warranty claims with prejudice and his express warranty claim without prejudice.

## I. Background

This case concerns several alleged failings of the Titan Prosthesis, which defendant manufactures and which plaintiff received via surgical implant [Doc. 1-1 ¶ 3].

### A. FDA Approval of the Titan Prosthesis[2]

The medical device now known as the Titan Prosthesis was originally owned and marketed by Mentor Corporation as the Mentor Alpha I Inflatable Penile Prosthesis [Doc. 10-1 p. 2]. Mentor intended the device for use by "male patients suffering from erectile dysfunction (impotence) who are considered to be candidates for implantation of a penile prosthesis" [*Id.*]. On February 7, 2000, Mentor submitted an application to the FDA for premarket approval ("PMA") of its device, which the FDA approved on July 14, 2000, subject to certain terms and "Conditions of Approval" [*Id.* at 2–9].

[2] The Court here relies upon and takes judicial notice of various publicly-available Food and Drug Administration ("FDA") documents, which are attached as Exhibits 1–10 to the declaration of defense counsel Leaf McGregor [Docs. 10, 10-1 through 10-10]. "'In determining whether to grant a Rule 12(b)(6) motion, the court primarily considers the allegations in the complaint, although matters of public record . . . also may be taken into account.'" *Amini v. Oberlin Coll.*, 259 F.3d 493, 502 (6th Cir. 2001) (quoting *Nieman v. NLO, Inc.*, 108 F.3d 1546, 1554 (6th Cir. 1997)); *see also Lozar v. Birds Eye Foods, Inc.*, 678 F. Supp. 2d 589, 599 (W.D. Mich. 2009) ("The court may also consider, without converting the 12(b)(6) motion into a motion for summary judgment, 'matters of public record . . . as long as the facts noticed are not subject to reasonable dispute.'") (quoting *Pakootas v. Teck Cominco Metals, Ltd.*, 632 F. Supp. 2d 1029, 1032 (E.D. Wash. 2009)).

These conditions required Mentor to, *inter alia*, only use certain pre-approved labeling, submit annual post-approval reports, and restrict advertising to approved uses of the device [*Id.* at 5–6]. Mentor also was obligated to submit a PMA supplement application "[b]efore making any change affecting the safety or effectiveness of the device" [*Id.* at 5]; *see also* 21 C.F.R. § 814.39(a) (placing "the burden for determining whether a supplement is required . . . primarily on the PMA holder"). The FDA issued a public Summary of Safety and Effectiveness Data for the Titan Prosthesis [Doc. 10-3], which disclosed the information upon which the FDA relied in granting it PMA status [Doc. 10-2].

In June 2006, defendant Coloplast Corporation informed the FDA that it had purchased the Titan Prosthesis from Mentor [*See* Doc. 10-8 p. 2 (indicating to defendant that "[a]ll previous regulatory requirements remain in effect and are now the responsibility of Coloplast")]. In addition, since the device first received PMA status in 2000, Mentor and defendant have collectively submitted multiple PMA supplements for the Titan Prosthesis, all of which the FDA approved [Docs. 10-5 through 10-7]. On June 13, 2008, for example, defendant received permission to add "a new one-touch release pump," along with other modifications, and to alter the device's labeling accordingly [Doc. 10-7 p. 2].

**B. Factual Allegations and Procedural History**

According to the complaint, Brian Parker, M.D., implanted a Titan Prosthesis into plaintiff on September 18, 2013 [Doc. 1-1 ¶ 3]. After the surgery, the device was "left in

a 'mainly deflated state'" [*Id.* ¶ 3]. Plaintiff returned to Dr. Parker's office a month later for instruction on the device's use; however, once the Titan Prosthesis was inflated, none of the medical personnel present were able to deflate it [*Id.* ¶ 4]. During a follow-up visit the next day, the same malfunction occurred and the device again did not fully deflate [*Id.* ¶ 5]. Dr. Parker eventually concluded, on October 31, 2013, that the device was "'nonfunctioning/poorly functioning" [*Id.* ¶ 6]. Plaintiff alleges these malfunctions caused him to suffer "injuries . . . requir[ing] professional medical care" and "great pain of body and mind; said injuries being permanent in nature" [*Id.* ¶¶ 8–9].

Almost a year later, plaintiff brought suit against defendant in the Circuit Court for Knox County, Tennessee [*Id.* at 3, 5]. Defendant timely removed to federal court, asserting diversity of citizenship pursuant to 28 U.S.C. § 1332 as the basis for the Court's subject matter jurisdiction [Doc. 1 ¶¶ 11–12]. On December 19, 2014, defendant filed the present motion to dismiss [Doc. 8], supporting memorandum of law [Doc. 9], and supporting declaration with attached FDA records [Docs. 10, 10-1 through 10-10]. After plaintiff failed to timely respond to the motion, defendant moved for either an order of dismissal or an order for plaintiff to show cause [Doc. 11 p. 2]. On June 3, 2015, the Court afforded plaintiff fourteen days to show cause why the action should not be dismissed [Doc. 12].

Responding *pro se* on June 17, 2015, plaintiff explained that his counsel, Steven L. Williams, never received a copy of the motion to dismiss because he "is not currently licensed in [this Court] and as such is not part of the electronic filing system" [Doc. 13 ¶ 4]. Plaintiff supported his response with an affidavit from Mr. Williams [Doc. 13-1] and requested thirty days to obtain substitute counsel and respond to defendant's motion to dismiss [Doc. 13 ¶ 7]. The Court granted plaintiff's request and ordered that he respond to defendant's motion within thirty days [Doc. 14].

That deadline has now passed, *see* Fed. R. Civ. P. 6(a)(1), and the record contains no further response from plaintiff. Defendant subsequently filed a Motion for Entry of Order of Dismissal based on plaintiff's continued failure to respond and the merits of its motion to dismiss [Doc. 15].[3]

## II. Standard of Review

Rule 8(a)(2) of the Federal Rules of Civil Procedure sets forth a liberal pleading standard. *Smith v. City of Salem*, 378 F.3d 566, 576 n.1 (6th Cir. 2004). It requires only "'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (alteration in

[3] Although the Motion for Entry of Order of Dismissal requests dismissal of all counts with prejudice [Doc. 15 ¶ 3], neither defendant's motion to dismiss [Doc. 8] nor its accompanying memorandum of law [Doc. 9] specifies whether dismissal should be with or without prejudice. As explained later in the opinion, the Court will dismiss all claims with prejudice except plaintiff's express warranty claim, which fails to state a claim due to an insufficiency in pleading rather than a legal bar to the cause of action. *See* 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 1998) (recommending dismissal without prejudice when a claim fails because of the formal insufficiency of the complaint, "regardless of how unpromising the initial pleading appears").

original) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). Detailed factual allegations are not required, but a party's "obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (alteration in original) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (alteration in original) (quoting *Twombly*, 550 U.S. at 557).

In deciding a Rule 12(b)(6) motion to dismiss, the Court must determine whether the complaint contains "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. In doing so, the Court "construe[s] the complaint in the light most favorable to the plaintiff, accept[s] its allegations as true, and draw[s] all reasonable inferences in favor of the plaintiff." *Directv, Inc. v. Treesh*, 487 F.3d 471, 476 (6th Cir. 2007) (citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556).

"Determining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679 (citation omitted). In addition, while the Court's analysis under Rule 12(b)(6) "'rests primarily upon the allegations of the complaint, matters of

public record, orders, items appearing in the record of the case, and exhibits attached to the complaint also may be taken into account.'" *Henry v. Chesapeake Appalachia, L.L.C.*, 739 F.3d 909, 912 (6th Cir. 2014) (quoting *Barany-Snyder v. Weiner*, 539 F.3d 327, 332 (6th Cir. 2008)); *see also Malin v. JPMorgan*, 860 F. Supp. 2d 574, 578 (E.D. Tenn. 2012) (citations omitted) (finding that taking judicial notice of matters of public record does not convert a Rule 12(b)(6) motion into a Rule 56 motion for summary judgment); *Signature Combs, Inc. v. United States*, 253 F. Supp. 2d 1028, 1040 n.5 (W.D. Tenn. 2003) (same).

## III. Analysis

Defendant argues that plaintiff's four state-law causes of action—design defect, failure to warn, and breach of express and implied warranties[4]—either are expressly preempted by federal law or otherwise fail to meet the pleading standard of Federal Rule of Civil Procedure 8(a)(2), as interpreted by the Supreme Court in *Twombly* and *Iqbal*

[4] Defendant interprets plaintiff's complaint as asserting these four specific causes of action [Doc. 8 ¶ 2–3]. The Court agrees with defendant's interpretation but notes that the complaint could also potentially be construed as asserting a manufacturing defect claim [*See* Doc. 1-1 ¶ 12 ("The non-functioning / poorly functioning penile prosthesis was defective and was placed into the stream of commerce . . . .")]. Such a claim—if asserted at all—might survive an MDA preemption challenge in some circumstances. *See Phillips v. Stryker Corp.*, No. 3:09-CV-488, 2010 WL 2270683, at *7 (E.D. Tenn. June 3, 2010) (denying motion to dismiss manufacturing defect claim where manufacturer allegedly deviated from FDA approval requirements). Plaintiff, however, has failed to plead sufficient factual matter to state a viable claim for relief on this basis.

[Doc. 9 p. 5, 16, 20].[5] For the reasons below, the Court agrees with defendant that all of plaintiff's claims fail as a matter of law and must be dismissed.

### A. Legal Background

The Food, Drug, and Cosmetic Act of 1938 provided for FDA premarket approval of new prescription drugs, but "it did not authorize any control over the introduction of new medical devices." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475 (1996) (citation omitted). States generally were given discretion to regulate the manner by which new medical devices entered the market. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). The Medical Device Amendments of 1976 ("MDA"),[6] however, "swept back some state obligations and imposed a regime of detailed federal oversight" for such devices. *Id.* at 316.

[5] Defendant also argues that plaintiff's claims for design defect and implied warranty fail under the Restatement (Second) of Torts § 402A cmt. k [Doc. 9 p. 17–19]. Comment k governs "[u]navoidably unsafe products" and provides that "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defective." Restatement (Second) of Torts § 402A cmt. k. Some courts have determined that inflatable penile prostheses constitute inherently dangerous products and have relied on comment k to dispose of design defect and implied warranty claims concerning such devices. *See, e.g.*, *Harwell v. Am. Med. Sys., Inc.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992) (noting comment k as an alternate basis for summary judgment on strict liability claims). The Court, however, may need to consider materials external to the pleadings and matters of public record to fully address this argument. *See Rodriguez v. Stryker Corp.*, No. 2:08-0124, 2011 WL 31462, at *6 (M.D. Tenn. Jan. 5, 2011) (discussing comment k in the summary judgment context); *Harwell*, 803 F. Supp. at 1300 (same); *see also* §402A cmt. k (stating that this designation depends on "the present state of human knowledge"). Regardless, because the Court will dismiss plaintiff's design defect and implied warranty claims on preemption grounds, the Court need not reach defendant's comment k argument.

[6] Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in 21 U.S.C. § 360c *et seq.*).

For example, the MDA created a three-tier classification system for devices, where the level of FDA scrutiny corresponds with the risk posed to human health. 21 U.S.C. § 360c(a)(1). Class I devices "pose little to no risk of injury" and require only "general controls"; Class II devices "pose greater risks" and require "special controls"; and Class III devices require strict pre-market oversight because they either support or sustain human life or pose a significant risk of harm. *Phillips*, 2010 WL 2270683, at *4 (quoting *Riegel*, 552 U.S. at 317) (internal quotation marks omitted). The Titan Prosthesis is unquestionably a Class III medical device. *See* 21 C.F.R. § 876.3350(b) (classifying all "penile inflatable implant[s]" as Class III medical devices).

The manufacturer of a Class III device must "provide the FDA with a 'reasonable assurance' that the device is both safe and effective" before the device may be sold. *Lohr*, 518 U.S. at 477 (quoting 21 U.S.C. § 360e(d)(2)). The PMA process used to provide such assurance is "a rigorous one" that requires approximately 1,200 hours of FDA review. *Id.* (citing *Hearings Before the Subcomm. on Health and the Env't of the H. Comm. on Energy & Commerce*, 100th Cong. 384 (1987)). The process "includes review of the device's proposed labeling" and may result in approval conditioned on "adherence to performance standards, restrictions upon sale or distribution, or compliance with other requirements." *Riegel*, 552 U.S. at 318–19 (citations omitted).

Not all Class III devices, however, undergo such scrutiny. "Class III medical devices that are 'substantially equivalent' to Class III devices previously introduced into the market . . . . are subject to the less rigorous § 510(k) process," which generally

requires an average of twenty hours of review. *Hafer v. Medtronic, Inc.*, — F. Supp. 3d —, 2015 WL 1648978, at *2 (W.D. Tenn. Apr. 13, 2015) (citing *Lohr*, 518 U.S. at 478–79). While the majority of new Class III devices today go through the § 510(k) process, *Riegel*, 552 U.S. at 317, the Titan Prosthesis instead received full PMA review and approval [Doc. 10-1 p. 2].

Devices that undergo the rigorous premarket approval process receive the benefit of the MDA's "express pre-emption provision." *Riegel*, 552 U.S. at 316, 522–23. Under that provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

Prior to 2008, it was unclear whether § 360k(a) expressly preempts state common-law causes of action in addition to conflicting state regulations. *Compare Lohr*, 518 U.S. at 501 (holding that § 510(k) "substantial equivalence" review did not impose device-specific regulations sufficient to trigger the preemption clause), *with Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424–25 (6th Cir. 2005) (holding that § 360k(a) preempted failure-to-warn and failure-to-recall claims for a device that received PMA status). In *Riegel*, however, the Supreme Court clarified that the PMA process—in contrast to the more

lenient § 510(k) process—did "impose[] 'requirements' under the MDA . . . . specific to individual devices" and therefore invoked the MDA's express preemption provision. 552 U.S. at 322–23. Accordingly, § 360k(a) serves to preempt any "state-law tort suits [that] would interfere with the requirements that the FDA impose[s] for a particular device through the extensive PMA process." *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 439 (6th Cir. 2010) (citing *Riegel*, 552 U.S. at 312, 323–25).

The *Riegel* Court set out a two-part test for determining whether a state-law claim interferes with the FDA's pre-market review process and is thus expressly preempted:

> A court . . . must first consider whether the federal government has established requirements applicable to the medical device at issue. If so, the court must then determine whether a plaintiff's claim is "based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal [requirements], and that relate to safety and effectiveness."

*Phillips*, 2010 WL 2270683, at *5 (second and third alterations in original) (citation omitted) (quoting *Riegel*, 552 U.S. at 321). Because "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application," devices that receive PMA status are subject to federal "requirement[s]" within the meaning of § 360k(a) so as to automatically satisfy the first prong of the test. *Riegel*, 552 U.S. at 323; *see also Starks v. Coloplast Corp.*, No. 13-3872, 2014 WL 617130, at *4 (E.D. Pa. Feb. 18, 2014) ("[P]remarket approval devices are subject to 'requirements' that are 'specific to individual devices.'"); *Dorsey v. Allergan, Inc.*, No. 3:08-0731, 2009 WL 703290, at *5 (M.D. Tenn. Mar. 11, 2009) (same).

### B. Analysis of Plaintiff's Claims

It is clear that the Titan Prosthesis received and has since maintained PMA status [Doc. 10-1 p. 2]. As a result, the federal government has definitively "established requirements applicable to the medical device at issue," *Phillips*, 2010 WL 2270683, at *5, and the first prong of the *Riegel* test is satisfied for all of plaintiff's claims, *see Cooley v. Medtronic, Inc.*, No. 09-30-ART, 2012 WL 1380265, at *3–5 (E.D. Ky. Apr. 20, 2012) (finding devices were "clearly subject to federal requirements because they received premarket approval from the FDA").

The Court now must analyze plaintiff's claims to determine whether they "rely upon 'any requirement' of [Tennessee] law applicable to the [Titan Prosthesis] that is 'different from, or in addition to[]' federal requirements and that 'relates to the safety or effectiveness of the device.'" *Riegel*, 552 U.S. at 323 (quoting 21 U.S.C. § 360k(a)). Courts in the Sixth Circuit have interpreted this second prong of the *Riegel* test to consist of three sub-elements: "(1) the existence of state law requirements applicable to the device, (2) that are different from or in addition to federal requirements, and (3) that relate to safety and effectiveness." *Kitchen v. Biomet, Inc.*, No. 13-18-HRW, 2014 WL 694226, at *3 (E.D. Ky. Feb. 21, 2014). The Court will address plaintiff's four causes of action in turn.

### 1. Design Defect

Plaintiff appears to assert a claim based on a design defect theory of products liability [*See* Doc. 1-1 ¶ 12 (alleging that "[t]he non-functioning / poorly functioning penile prosthesis was defective and was placed into the stream of commerce . . . .")]. In *Riegel*, the Supreme Court held that the MDA's "reference to a State's 'requirements' includes its common-law duties." 552 U.S. at 324. In other words, because state tort law causes of action create legal duties for device manufacturers, these claims "do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Id.* at 323–24 (alteration in original) (citing *Lohr*, 518 U.S. at 503–05, 512). The Supreme Court also observed that "[s]afety and effectiveness are the very subjects of" the plaintiffs' strict liability, negligence, and implied warranty claims. *Id.* at 323. Accordingly, the first and third elements of this prong of the test are satisfied, and the claim will be preempted if it imposes legal obligations different from or in addition to federal requirements—namely, the conditions and restrictions set forth by the PMA process.

The Court notes, however, that this second element "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330 (quoting *Lohr*, 518 U.S. at 495). Courts have allowed such parallel claims to survive MDA preemption when the plaintiff expressly pleads a violation of an FDA regulation specific to the device or of one of the Good Manufacturing Practices

("GMPs") applicable to all devices. *See, e.g.*, *Howard*, 382 F. App'x at 441 (holding that a negligence per se claim based on a GMP violation constituted a non-preempted parallel claim).

Plaintiff's complaint does not suggest defendant has failed to conform to the FDA requirements prescribed by its premarket approval or has deviated from or violated any federal statute or regulation [*See generally* Doc. 1-1]. Therefore, the Court finds the exception for parallel claims does not apply, the second element is met, and the claim is preempted by the MDA. *See Starks*, 2014 WL 617130, at *5 (dismissing state-law design defect claim as preempted, reasoning that the plaintiff did not assert any violation of FDA requirements, regulations, or statutes); *Malbroux v. Jancuska*, No. 11-421, 2011 WL 3816104, at *1, 3 (W.D. La. Aug. 29, 2011) (dismissing claim that penile prosthesis was "defective because it never worked properly," reasoning that a jury verdict in plaintiff's favor for a design defect would impliedly require more of defendant than what the FDA already required (citation omitted)); *Dorsey*, 2009 WL 703290, at *7 (reasoning that premarket approval is a bar to the plaintiff's strict liability claim "because the FDA has determined that the implants at issue are reasonably safe for consumers and there is no suggestion that the implants she received were somehow different than those ultimately approved by the FDA").

**2. Failure to Warn**

Plaintiff's complaint next asserts that defendant failed to properly warn him of the dangers of the Titan Prosthesis [Doc. 1-1 ¶ 11 ("Defendant failed to warn the Plaintiff of potential problems such as pain and mechanical failure . . . .")]. This theory, however, fails to state a claim for the same reasons as plaintiff's design defect claim. After all, a warnings defect claim is simply another species of strict products liability, along with manufacturing and design defect claims. *See Lee v. Metro. Gov't of Nashville & Davidson Cnty.*, 596 F. Supp. 2d 1101, 1127 (M.D. Tenn. 2009) ("[I]n addition to arguing that a product suffers from a defect in design or manufacture, the plaintiff can also assert that the product suffers from a warnings defect."). The *Riegel* Court's reasoning thus applies. As to the first and third elements, the failure-to-warn claim is a state tort law cause of action that imposes requirements applicable to the device at issue, and these requirements relate to the safety and effectiveness of the device. *See Riegel*, 552 U.S. at 323–25.

Regarding the second element, the FDA has already approved specific warnings and instructions for the Titan Prosthesis [*see* Docs. 10-9, 10-10], and the complaint does not assert that defendant has deviated from this accepted language in any respect [*see generally* Doc. 1-1]. Plaintiff's failure-to-warn claim therefore would impose liability for defendant's failure to include warnings or instructions that are not required under federal law. *See Sadler v. Advanced Bionics, Inc.*, 929 F. Supp. 2d 670, 682 (W.D. Ky. 2013) ("To the extent [p]laintiffs are alleging that . . . . the labels must include some

information in addition to or different from what the FDA and the FDCA prescribe[, that claim] is expressly preempted under the second step of the *Riegel* analysis." (citations omitted)); *see also Cupek*, 405 F.3d at 424 ("Any claim, under state law, then, that Defendant failed to warn patients beyond warnings required by the FDA . . . would constitute state requirements 'different from' or 'in addition to' the requirements of the federal PMA application and supplement process."). In sum, all three elements of the second prong of the *Riegel* test are satisfied, and plaintiff's failure-to-warn claim will be dismissed as preempted.

**3. Breach of Implied Warranty**

Plaintiff's complaint also contains a bare assertion that "[d]efendant breached warranties, both express and implied, said breaches resulting in injury and pain of body and mind" to plaintiff [Doc. 1-1 ¶ 13]. As an initial matter, plaintiff's implied warranty claim appears to fail under Tennessee law. The Tennessee Product Liability Act ("TPLA") incorporates breach of implied warranty into its definition of a products liability action, Tenn. Code Ann. § 29-28-102(6), and provides that "[a] manufacturer or seller of a product shall not be liable . . . unless the product is determined to be in a defective condition or unreasonably dangerous," § 29-28-105(a). In other words, "[a] finding that a product was not defective or unreasonably dangerous forecloses an implied warranty claim under the TPLA." *Rodriguez v. Stryker Corp.*, No. 2:08-0124, 2011 WL 31462, at *11 (M.D. Tenn. Jan. 5, 2011) (citing *Irion v. Sun Lighting, Inc.*, No. M2002-00766-COA-R3-CV, 2004 WL 746823, at *18 (Tenn. Ct. App. Apr. 7, 2004)). Here, the

FDA's grant of PMA status to the Titan Prosthesis may suffice as a determination that the device was not defectively designed or unreasonably dangerous, thereby foreclosing plaintiff's implied warranty claim under Tennessee law.

As for preemption, an implied warranty claim was at issue in *Riegel*, 552 U.S. at 320, and the Supreme Court held that all of the plaintiffs' common-law claims imposed requirements relating to safety and effectiveness, *id.* at 323–25. Accordingly, the first and third elements of the *Riegel* test are satisfied. And the Court finds these Tennessee requirements differ from or add to federal requirements, which satisfies the second element and results in preemption. *See Cooley*, 2012 WL 1380265, at *4 (finding implied warranty claim preempted "because a jury would have to find that the devices were not safe and effective, a finding that would be contrary to the FDA's approval" (internal quotation marks and citations omitted)); *Kitchen*, 2014 WL 694226, at *7 ("'A state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it. Accordingly, such a claim is preempted.'") (quoting *Enlow v. St. Jude Med., Inc.*, 210 F. Supp. 2d 853, 862 (W.D. Ky. 2001)); *cf. Hawkins v. Medtronic, Inc.*, 909 F. Supp. 2d 901, 910–11 (S.D. Ohio Sept. 24, 2012) (denying motion to dismiss implied warranty claim when "it [was] clear from the allegations that Plaintiff's claim is in fact premised on the theory that Defendant violated federal law").

**4. Breach of Express Warranty**

As noted above, plaintiff also claims defendant breached express warranties [Doc. 1-1 ¶ 13]. Such a claim may survive an MDA preemption challenge as it "'arise[s] from the representations of the parties and[']. . . may 'not necessarily interfere with the operation of the PMA.'" *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) (first alteration in original) (quoting *Mitchell v. Collagen Corp.*, 126 F.3d 902, 915 (7th Cir. 1997)). In other cases, a plaintiff's "allegations of a breached warranty of safety and effectiveness directly contradict the FDA's analysis of safety and effectiveness" and lead to preemption under § 360k(a). *Hafer*, 2015 WL 1648978, at *16.

Here, plaintiff has failed to plead his express warranty claim with sufficient detail to allow the Court to make this determination [*See* Doc. 1-1 ¶ 13 (stating only that "[d]efendant breached warranties, both express and implied")]. Plaintiff has offered nothing more than a "'naked assertion[]' devoid of 'further factual enhancement,'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557)), and the Court will dismiss this claim for failure to satisfy Federal Rule of Civil Procedure 8(a)(2). But given the general policy of deciding cases based on the substantive rights involved rather than technicalities, the Court chooses to dismiss this claim without prejudice. *See Starks*, 2014 WL 617130, at *7 (dismissing express warranty claim without prejudice for failure to allege all necessary elements); 5B Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 1357 (3d ed. 1998) (encouraging dismissal without prejudice

"even when the district judge doubts that the plaintiff will be able to overcome the shortcomings in the initial pleading").

## IV. Conclusion

For the reasons set forth herein, plaintiff's claims for design defect, failure to warn, and breach of implied warranty will be dismissed with prejudice, and plaintiff's claim for breach of express warranty will be dismissed without prejudice. Accordingly, Defendant's Motion to Dismiss [Doc. 8] will be **GRANTED**, and Defendant's Motion for Entry of Order of Dismissal [Doc. 15] will be **GRANTED in part** and **DENIED in part**, as the Court declines to dismiss the express warranty claim with prejudice [*see id.* ¶ 3]. The complaint in this matter [Doc. 1-1] will be **DISMISSED**, and the Clerk of Court will be **DIRECTED** to **CLOSE** this case.

ORDER ACCORDINGLY.

s/ Thomas A. Varlan
CHIEF UNITED STATES DISTRICT JUDGE